K010377

MiniMed®
Advancing solutions in diabetes

APR - 5 2001

Section C. 510(k) Summary

Submitter: MiniMed® Inc. 18000 Devonshire St., Northridge, CA 91325

Contact: Jennifer Lyons (818) 576-5189

Name of Device: MiniMed Sil-serter™ infusion set insertion system, model 385

Predicate Device: MiniMed Sof-serter® infusion set insertion system, model 300

Description of the New Device: The MiniMed Sil-serter is a manually operated, spring-loaded infusion set insertion device. It is similar in features and intended use to the MiniMed Sof-serter infusion set insertion system. The device has been designed for use exclusively with the Silhouette family of infusion sets, made for MiniMed Inc. by Maersk Medical. The device is contraindicated for use with other infusion sets.

Intended Use of the New Device: The MiniMed Sil-serter is intended as an aid for insertion of the Silhouette family of infusion sets.

Comparison of the Technological Features of the New Device and Predicate Device: Technologically, both insertion devices are spring-driven devices that require the user to load the infusion set into a carrier, compress a spring, then activate the device by depressing a trigger button. Both devices are made of plastic with metal springs. The differences between the new device and the predicate device are limited to differences required for compatibility with the specific infusion set to be inserted. These modifications do not affect the safety or effectiveness of the device.

Signed,

Jennifer Lyons 2/7/01

Jennifer Lyons date
Regulatory Affairs Specialist
MiniMed Inc.

®MiniMed, Silhouette, and Sof-serter are Registered Trademarks of MiniMed Inc.
™Sil-serter is a Trademark of MiniMed Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K010377
Trade Name: MiniMed® Sil-serter™ Infusion Set Insertion System, Model 385
Regulatory Class: II
Product Code: KZH
Dated: February 7, 2001
Received: February 8, 2001

Dear Ms. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4696. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010377

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INDICATIONS FOR USE

510(k) Number:

Device Name: MiniMed Sil-serter infusion set insertion system, model 385

Indications for Use: The Sil-serter infusion set insertion system (Sil-serter), model 385, is indicated as an aid for insertion of the Silhouette family of infusion sets.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucerite
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010377

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